Diethyl ether soluble matter other than that specified, not more than 2 parts per million, using added 2-(2-quinolinyl)-1*H*-indene-1,3 (2*H*)-dione for calibration.
Lead (as Pb), not more than 20 parts per million.
Arsenic (as As), not more than 3 parts per million.
Mercury (as Hg), not more than 1 part per million.
Total color, not less than 85 percent.

(c) *Uses and restrictions.* The color additive D&C Yellow No. 10 may be safely used for coloring drugs generally in amounts consistent with current good manufacturing practice.

(d) *Labeling.* The label of the color additive and any mixtures prepared therefrom and intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter.

(e) *Certification.* All batches of D&C Yellow No. 10 shall be certified in accordance with regulations in part 80 of this chapter.

[48 FR 39219, Aug. 30, 1983, as amended at 49 FR 8432, Mar. 7, 1984]

§ 74.1711 D&C Yellow No. 11.

(a) *Identity.* (1) The color additive D&C Yellow No. 11 is principally 2-(2-quinolyl)-1,3-indandione.

(2) Color additive mixtures, for drug use made with D&C Yellow No. 11 may contain only those diluents that are suitable and that are listed in part 73 of this chapter as safe for use in color additive mixtures for coloring externally applied drugs.

(b) *Specifications.* D&C Yellow No. 11 shall conform to the following specifications and shall be free from impurities, other than those named, to the extent that such other impurities may be avoided by good manufacturing practice:

Volatile matter (at 135 °C), not more than 1 percent.
Ethyl alcohol-insoluble matter, not more than 0.4 percent.
Phthalic acid, not more than 0.3 percent.
Quinaldine, not more than 0.2 percent.
Subsidiary colors, not more than 5 percent.
Lead (as Pb), not more than 20 parts per million.
Arsenic (as As), not more than 3 parts per million.
Mercury (as Hg), not more than 1 part per million.
Total color, not less than 96 percent.

(c) *Uses and restrictions.* D&C Yellow No. 11 may be safely used in externally applied drugs in amounts consistent with good manufacturing practice.

(d) *Labeling.* The label of the color additive and any mixtures prepared therefrom intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter.

(e) *Certification.* All batches of D&C Yellow No. 11 shall be certified in accordance with regulations in part 80 of this chapter.

Subpart C—Cosmetics

§ 74.2052 D&C Black No. 2.

(a) *Identity.* The color additive D&C Black No. 2 is a high-purity carbon black prepared by the oil furnace process. It is manufactured by the combustion of aromatic petroleum oil feedstock and consists essentially of pure carbon, formed as aggregated fine particles with a surface area range of 200 to 260 meters $(m)^2$/gram.

(b) *Specifications.* D&C Black No. 2 shall conform to the following specifications and shall be free from impurities other than those named to the extent that such other impurities may be avoided by good manufacturing practice:

(1) Surface area by nitrogen BET (Brunauer, Emmett, Teller) method, 200 to 260 m^2/gram.

(2) Weight loss on heating at 950 °C for 7 minutes (predried for 1 hour at 125 °C), not more than 2 percent.

(3) Ash content, not more than 0.15 percent.

(4) Arsenic (total), not more than 3 milligrams per kilogram (mg/kg) (3 parts per million).

(5) Lead (total), not more than 10 mg/kg (10 parts per million).

(6) Mercury (total), not more than 1 mg/kg (1 part per million).

(7) Total sulfur, not more than 0.65 percent.

(8) Total PAHs, not more than 0.5 mg/kg (500 parts per billion).

(9) Benzo[*a*]pyrene, not more than 0.005 mg/kg (5 parts per billion).

(10) Dibenz[*a*,*h*]anthracene, not more than 0.005 mg/kg (5 parts per billion).

(11) Total color (as carbon), not less than 95 percent.

(c) *Uses and restrictions.* D&C Black No. 2 may be safely used for coloring the following cosmetics in amounts consistent with current good manufacturing practice: Eyeliner, brush-on-brow, eye shadow, mascara, lipstick, blushers and rouge, makeup and foundation, and nail enamel.

(d) *Labeling.* The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(e) *Certification.* All batches of D&C Black No. 2 shall be certified in accordance with regulations in part 80 of this chapter.

[69 FR 44930, July 28, 2004, as amended at 72 FR 10357]

§ 74.2053 D&C Black No. 3.

(a) *Identity.* The color additive D&C Black No. 3 is a washed bone char prepared from calcined cattle bones. The bones are twice heated in excess of 700 °C for at least 6 hours.

(b) *Specifications.* D&C Black No. 3 shall conform to the following specifications and shall be free from impurities other than those named, to the extent that such other impurities may be avoided by current good manufacturing practices:

(1) Calcium hydroxyapatite (CaO and P_2O_5), not less than 75 percent and not more than 84 percent;

(2) Elemental carbon, not less than 7 percent;

(3) Moisture, not more than 7 percent;

(4) Silica (SiO_2), not more than 5 percent;

(5) Arsenic, not more than 3 milligrams (mg)/kilogram (kg) (3 parts per million (ppm));

(6) Lead, not more than 10 mg/kg (10 ppm); and

(7) Total polycyclic aromatic hydrocarbons (PAHs), not more than 5 mg/kg (5 ppm).

(c) *Uses and restrictions.* Cosmetics containing D&C Black No. 3 must comply with § 700.27 of this chapter with respect to prohibited cattle materials in cosmetic products. D&C Black No. 3 may be safely used for coloring the following cosmetics in amounts consistent with current good manufacturing practice: Eyeliner, eye shadow, mascara, and face powder.

(d) *Labeling.* The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(e) *Certification.* All batches of D&C Black No. 3 shall be certified in accordance with regulations in part 80 of this chapter.

[72 FR 33666, June 19, 2007]

§ 74.2101 FD&C Blue No. 1.

(a) *Identity.* The color additive FD&C Blue No. 1 is principally the disodium salt of ethyl[4-[*p*-[ethyl(*m*-sulfobenzyl)amino]-α-(*o*-sulfophenyl)benzylidene]-2,5-cyclohexadien-1-ylidene](*m*-sulfobenzyl)ammonium hydroxide inner salt with smaller amounts of the isomeric disodium salts of ethyl[4-[*p*-[ethyl(*p*-sulfobenzyl)amino]-α-(*o*-sulfophenyl)benzylidene]-2,5-cyclohexadien-1-ylidene](*p*-sulfobenzyl)ammonium hydroxide inner salt and ethyl[4-[*p*-[ethyl(*o*-sulfobenzyl)amino]-α-(*o*-sulfophenyl)benzylidene]-2,5-cyclohexadien-1-ylidene](*o*-sulfobenzyl)ammonium hydroxide inner salt. Additionally, FD&C Blue No. 1 is manufactured by the acid catalyzed condensation of one mole of sodium 2-formylbenzenesulfonate with two moles from a mixture consisting principally of 3-[(ethylphenylamino)methyl] benzenesulfonic acid, and smaller amounts of 4-[(ethylphenylamino)methyl] benzenesulfonic acid and 2-[(ethylphenylamino)methyl] benzenesulfonic acid to form the leuco base. The leuco base is then oxidized with lead dioxide and acid, or with dichromate and acid, or with manganese dioxide and acid to form the dye. The intermediate sodium 2-formylbenzenesulfonate is prepared from 2-chlorobenzaldehyde and sodium sulfite.

(b) *Specifications.* (1) The color additive FD&C Blue No. 1 shall conform in specifications to the requirements of § 74.101(b).

(2) FD&C Blue No. 1 Aluminum Lake shall be prepared in accordance with the requirements of § 82.51 of this chapter.